

DENTO VIRACTIS 77 WIPES - MEDICAL DEVICES - 1526-027-2

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : DENTO VIRACTIS 77 WIPES - MEDICAL DEVICES
Product code : 1526-027-2.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Wipes impregnated with a disinfecting detergent for cleaning and disinfecting surfaces and invasive and non-invasive medical devices by wet wiping.

1.3. Details of the supplier of the safety data sheet

Registered company name : CADENCE.
Address : 2 bis, chemin du Loup.93290.TREMBLAY-EN-FRANCE.FRANCE.
Telephone : +33 (0)1 45 91 31 82. Fax : +33 (0)1 48 65 67 23.
info@cfpm-medical.fr

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Flammable liquid, Category 2 (Flam. Liq. 2, H225).
Eye irritation, Category 2 (Eye Irrit. 2, H319).
May produce an allergic reaction (EUH208).
Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).

2.2. Label elements

Biocidal detergent mixture (see section 15).
The mixture is a disinfectant cleaner product for medical device use.

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS02

GHS07

Signal Word :

DANGER

Additional labeling :

EUH208 Contains D-LIMONENE. May produce an allergic reaction.

Hazard statements :

H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements - General :

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P273 Avoid release to the environment.

Precautionary statements - Response :

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

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Precautionary statements - Storage :

P403 + P235 Store in a well-ventilated place. Keep cool.

Precautionary statements - Disposal :

P501 Dispose of contents/container as hazardous waste.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
CAS: 64-17-5 EC: 200-578-6 REACH: 01-2119457610-43 ETHYL ALCOHOL	GHS07, GHS02 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319	[1]	50 \leq x % < 100
CAS: 2372-82-9 EC: 219-145-8 REACH: 01-2119980592-29 N-(3-AMINOPROPYL)-N-DODECYLPROPAN E-1,3-DIAMINE	GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT RE 2, H373 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 1		0 \leq x % < 2.5
CAS: 5989-27-5 EC: 227-813-5 REACH: 01-2119529223-47 D-LIMONENE	GHS08, GHS02, GHS07, GHS09 Dgr Asp. Tox. 1, H304 Flam. Liq. 3, H226 Skin Irrit. 2, H315 Skin Sens. 1B, H317 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		0 \leq x % < 2.5

(Full text of H-phrases: see section 16)

Information on ingredients :

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

In the event of an allergic reaction, seek medical attention.

In the event of swallowing :

Keep the person exposed at rest. Do not force vomiting.

Seek medical attention, showing the label.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

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4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Flammable.

Chemical powders, carbon dioxide and other extinguishing gas are suitable for small fires.

5.1. Extinguishing media

Keep packages near the fire cool, to prevent pressurised containers from bursting.

Suitable methods of extinction

In the event of a fire, use :

- sprayed water or water mist
- water with AFFF (Aqueous Film Forming Foam) additive
- halon
- foam
- multipurpose ABC powder
- BC powder
- carbon dioxide (CO₂)

Prevent the effluent of fire-fighting measures from entering drains or waterways.

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

5.3. Advice for firefighters

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Because of the organic solvents contained in the mixture, eliminate sources of ignition and ventilate the area.

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

If the product contaminates waterways, rivers or drains, alert the relevant authorities in accordance with statutory procedures

Use drums to dispose of collected waste in compliance with current regulations (see section 13).

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Fire prevention :

Handle in well-ventilated areas.

Vapours are heavier than air. They can spread along the ground and form mixtures that are explosive with air.

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Prevent the formation of flammable or explosive concentrations in air and avoid vapor concentrations higher than the occupational exposure limits.

Prevent the accumulation of electrostatic charges with connections to earth.

Use the mixture in premises free of naked flames or other sources of ignition and ensure that electrical equipment is suitably protected.

Keep packages tightly closed and away from sources of heat, sparks and naked flames.

Do not use tools which may produce sparks. Do not smoke.

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid eye contact with this mixture.

The opened packaging must be carefully closed.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep out of reach of children.

Keep the container tightly closed in a dry, well-ventilated place.

Keep away from all sources of ignition - do not smoke.

Keep well away from all sources of ignition, heat and direct sunlight.

Avoid accumulation of electrostatic charges.

The floor must be impermeable and form a collecting basin so that, in the event of an accidental spillage, the liquid cannot spread beyond this area.

Store at a temperature between 5°C and 35°C.

Packaging

Always keep in packaging made of an identical material to the original.

Keep only in the original container.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

Occupational exposure limits :

- UK / WEL (Workplace exposure limits, EH40/2005, 2011) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm 1920 mg/m ³	- ppm - mg/m ³			

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Provide eyewash stations in facilities where the product is handled constantly.

Wearing safety glasses is not mandatory. If your protocols recommend wearing, use eye protection designed against liquid splashes.

- Hand protection

Wearing protective gloves is not mandatory. If your protocols recommend wearing, use appropriate protective gloves that are resistant to chemicals in accordance with NF EN374.

These gloves must comply with standard NF EN374.

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

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SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	Fluid liquid.
White wipes impregnated with a colorless solution.	
Odour:	Synthetic grapefruit scent.

Important health, safety and environmental information

pH :	Not relevant.
Boiling point/boiling range :	> 35°C
Flash Point :	22.00 °C.
Vapour pressure (50°C) :	Not relevant.
Density :	Not stated.
Water solubility :	Dilutable.
Melting point/melting range :	Not relevant.
Self-ignition temperature :	Not relevant.
Decomposition point/decomposition range :	Not relevant.
pH of the impregnating solution:	7.00 +/- 0.50.
Density of the impregnating solution:	0.887 +/- 0.01 g/mL.

9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

When exposed to high temperatures, the mixture can release hazardous decomposition products, such as carbon monoxide and dioxide, fumes and nitrogen oxide.

10.4. Conditions to avoid

Any apparatus likely to produce a flame or to have a metallic surface at high temperature (burners, electric arcs, furnaces etc.) must not be allowed on the premises.

Avoid :

- accumulation of electrostatic charges.
- heating
- heat
- flames and hot surfaces
- frost

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Splashes in the eyes may cause irritation and reversible damage

11.1.1. Substances

Acute toxicity :

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)
Oral route : LD50 = 261 mg/kg

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Species : Rat
OECD Guideline 401 (Acute Oral Toxicity)

Skin corrosion/skin irritation :

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)
Species : Rabbit
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Respiratory or skin sensitisation :

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)
Buehler Test : Non-sensitiser.
Species : Guinea pig
REACH Method B.6 (Skin Sensitisation)

Germ cell mutagenicity :

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)
No mutagenic effect.
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Ames test (in vitro) : Negative.

11.1.2. Mixture

Acute toxicity :

Species : Rat
LD50 > 2000 mg/kg

Skin corrosion/skin irritation :

Irritation : No observed effect.
Average score = 0
Duration of exposure : 72 h
Species : Rabbit

Serious damage to eyes/eye irritation :

Causes serious eye irritation.

Corneal haze : Average score = 2
Duration of exposure : 72 h
Species : Rabbit

Iritis : Average score = 1.5
Duration of exposure : 72 h
Species : Rabbit

Conjunctival redness : Average score = 3
Duration of exposure : 72 h
Species : Rabbit

Conjunctival oedema : Average score = 1
Duration of exposure : 72 h
Species : Rabbit

Respiratory or skin sensitisation :

Contains at least one sensitising substance. May cause an allergic reaction.

Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.
Species : Guinea pig

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 64-17-5 : IARC Group 1 : The agent is carcinogenic to humans.

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SECTION 12 : ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.1.1. Substances

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Fish toxicity : 0.1 < LC50 <= 1 mg/l
Factor M = 1
Species : Danio rerio
Duration of exposure : 96 h
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : 0.01 < EC50 <= 0.1 mg/l
Factor M = 10
Species : Daphnia magna
Duration of exposure : 48 h
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

0,01 < NOEC <= 0,1 mg/l
Species : Daphnia magna
Duration of exposure : 21 days
OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity : 0.01 < ECr50 <= 0.1 mg/l
Factor M = 10
Species : Pseudokirchnerella subcapitata
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

0,001 < NOEC <= 0,01 mg/l
Factor M = 1
Species : Pseudokirchnerella subcapitata
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

Surfactants in this preparation comply with the standards of biodegradability as defined in Regulation (EC) No 648/2004 on detergents.

The data proving this statement shall be made available to the competent authorities of the Member States and shall be supplied to them at their express request or at the request of the detergent manufacturer.

12.2.1. Substances

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Biodegradability : Rapidly degradable.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

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SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2017 - IMDG 2016 - ICAO/IATA 2017).

14.1. UN number

3175

14.2. UN proper shipping name

UN3175=SOLIDS or mixtures of solids (such as preparations and wastes) CONTAINING FLAMMABLE LIQUID, N.O.S. having a flash-point up to 60 °C
(ethyl alcohol)

14.3. Transport hazard class(es)

- Classification :



4.1

14.4. Packing group

II

14.5. Environmental hazards

-

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	4.1	F1	II	4.1	40	1 kg	216 274 601	E2	2	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	4.1	-	II	1 kg	F-A,S-I	216 274	E2

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	4.1	-	II	445	15 kg	448	50 kg	A46	E2
	4.1	-	II	Y441	5 kg	-	-	A46	E2

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No data available.

SECTION 15 : REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2018/669 (ATP 11)

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- Container information:

No data available.

- Particular provisions :

No data available.

- Labelling for detergents (EC Regulation No. 648/2004,907/2006) :

- less than 5 % : amphoteric surfactants
- disinfectants
- perfumes
- allergenic fragrances :
d-limonene
linalool

- Labelling for biocidal products (Regulation 1896/2000, 1687/2002, 2032/2003, 1048/2005, 1849/2006, 1451/2007 and Directive 98/8/EC) :

Name	CAS	%	Product-type
ETHYL ALCOHOL	64-17-5	620.00 g/kg	02 04
N-(3-AMINOPROPYL)-N-DODECYLPROPAN E-1,3-DIAMINE	2372-82-9	1.50 g/kg	02 04

Product-type 2 : Disinfectants and algacides not intended for direct application to humans or animals.

Product-type 4 : Food and feed area.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Version PRO.

Wording of the phrases mentioned in section 3 :

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H304	May be fatal if swallowed and enters airways.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure .
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Abbreviations :

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS02 : Flame

GHS07 : Exclamation mark

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.